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(54) Title: A MULTIPLE LAYERED ANTIMICROBIAL OR ANTIVIRAL GLOVE

(57) Abstract

The present invention involves an antiviral or antimicrobial surgical or examination glove. The glove comprises an elastomeric body in the shape of a hand having a inner surface and an outer surface. The inner surface comprises a hydrophilic/hydrogel polymer coating containing an antiviral or antimicrobial agent. The outer surface comprises a fluoroelastomer coating which blocks bacteria and viruses and is hydrophobic to bodily fluids.

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A MULTIPLE LAYERED ANTIMICROBIAL OR ANTIVIRAL GLOVE

FIELD OF THE INVENTION

This invention relates to a multiple layered glove having antimicrobial or antiviral properties. More particularly, the multiple layered glove has an outer coating of a fluoroelastomer and a inner hydrophilic coating containing a antimicrobial or antiviral agent.

BACKGROUND AND PRIOR ART

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Polymers containing fluorine are known for their extraordinary toughness and resistance to heat, cold, erosion, abrasion, solvents, weathering and chemical attack. See U.S. Reissue Patent No. 24,856. For example, U.S. Patent No. 4,555,543 discloses a fluoroplastic resin dispersion modified by the addition of a fluoroelastomer latex yielding a fluid coating or casting composition.

- U.S. Patent No. 4,214,321 discloses a glove that can be used to protect workers from a large number of chemicals and vapors. The glove has an outer layer of a fluorocarbon resin or a plasticized polyester resin which is flexible, solvent and abrasion resistant, a pin-hole free aluminum-foil middle layer and a inner heat sealable thermoplastic polymer material of polyethylene or polypropylene resin.
- U.S. Patent No. 4,943,473 discloses fire and chemical resistant materials that can be used for gloves. These materials are produced by laminating a fluoropolymer containing film onto one or both sides of a flexible substrate. These materials retain their flexibility or suppleness and show enhanced resistance to chemical permeation and degradation.
- 30 U.S. Patent No. 5,194,335 discloses a coating or casting composition comprising a fluoroplastic resin

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dispersion modified by the addition of a fluoroelastomer latex.

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For decades, attempts have been made to improve the donability of surgeon's gloves. Surgeon's gloves tend to have more critical requirements then examination gloves. Typically surgeon's like to don their gloves after "scrubbing up, " without drying their However, most surgeon's gloves are difficult to Several attempts have been made to don with wet hands. improve the donability of surgeon's gloves.

One attempt to improve the donability of surgeon's gloves involved placing a slip coating on the inside surface of the glove. For example, U.S. Patent Nos. 3,286,011 and 3,411,982 disclose a process for making a glove having a slip dip rubber-resin coating on the inside or outside surface of the glove. The slip dip rubber-resin coating comprises a rubber and resin latex. The resins disclosed as being suitable for use in the invention are: acrylic-type polymers and copolymers, vinyl acetate polymers and copolymers, polyethylene, polyvinyl acetals, polyvinyl chloride or copolymers of vinyl chloride, styrene-acrylonitrile resins and high styrene-butadiene copolymer resins.

Other slip coatings are disclosed in U.S. Patent 25 Nos. 3,856,561, 3,919,442, 3,967,014 and 4,082,862. U.S. Patent No. 3,856,561 discloses a rubber article having a slip coating. The slip coating is a vinylchloride-alkyl acrylate copolymer or a vinylidene chloride-alkyl acrylate copolymer. In U.S. Patent No. 3,919,442, the slip coating comprises a first resin copolymer component consisting of a vinyl chloridealkyl acrylate copolymer, a vinylidene chloride-alkyl acrylate copolymer and a vinyl acetate-alkyl acrylate copolymer and a second resin copolymer consisting of a vinyl chloride-vinyl ester copolymer and a vinylidene chloride-vinyl ester copolymer. U.S. Patent No.

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3,967,014, discloses a method for providing an essentially rubber free slip coating on a rubber surface by contacting a rubber surface with the slip coating disclosed in U.S. Patent No. 3,919,442 and permitting said coating to form a resin slip coating on the rubber surface. U.S. Patent No. 4,082,862 discloses a process for producing rubber articles having a slip coating wherein a form is first coated with a release agent, then coated with a slip coating composition deposited on the release agent and a rubber 10 substrate deposited over the slip coating. coating comprises of a non-elastomeric synthetic polymer component exhibiting an elongation of below about 20% and a coefficient of friction of up to about 0.20.

U.S. Patent 5,084,514 discloses a polymer latex for making gloves that has good donning and duffing The glove is a terpolymer of characteristics. carboxylated butadiene/acrylonitrile and methacrylic acid.

In addition to the slip coatings described above, hydrophilic coatings have been used to coat the inside surface of surgeon's gloves to facilitate donning. Many hydrophilic monomers are known in the art such as hydroxy alkyl acrylates, hydroxy alkyl methacrylates, vinyl lactams (eg. vinyl pyrrolidone), acrylamide and its derivatives, and ethylene oxide, just to name a few.

U.S. Patent No. 3,813,695 (the "Podell" patent) describes a surgeon's glove in which the glove material 30 is formed of a laminate consisting of an outer layer of a flexible material and an inner layer of hydrophilic plastic material (such as a hydrogel polymer), wherein the inner and outer layers are bonded together.

U.S. Patent No. 4,482,577 discloses a method of coating a vulcanized rubber article with a hydrophilic 5

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polymer. The process involves dipping the rubber glove into a high concentration (95-100%) of sulfuric acid, washing the glove and then immersing the glove in a hydrophilic polymer.

U.S. Patent Nos. 4,499,154 and 4,575,476 describe a surgeon's glove in which the glove material is formed of a laminate comprising of an outer flexible layer and a lubricating polymer. Examples of a lubricating polymer disclosed are copolymers of 2-hydroxyethyl methacrylate (HEMA) with methacrylic acid (MAA) or with 2-ethylhexyl acrylate (EHA) or with both methacrylic acid and 2-ethylhexyl acrylate. The hydrogel coating is further treated with a surfactant or long-chain fatty amine. It is believed that the surfactant or long-chain fatty amine enhances the lubricity of the innerlayer with respect to damp hands.

U.S. Patent No. 4,526,579 discloses a method of grafting a hydrophilic polymer onto the surface of a natural rubber article.

U.S. Patent No. 4,589,873 discloses a method for applying a hydrophilic polymer coating directly on to a substrate in order to provide a lubricous surface. Any polymeric substrate can be used. The substrate is contacted with a solution of the hydrophilic polymer in a suitable solvent. Any applying solvent in which the hydrophilic polymer is soluble can be used. The solvent is then removed from the substrate leaving only the hydrophilic coating.

U.S. Patent No. 5,069,965 describes rubber and vinyl articles having improved slip coatings. These rubber and vinyl articles have rubber-free extensible adherent slip coatings. One of the slip coatings disclosed is composed or the reaction product of about 55 to 80 mole % of a vinyl halide, about 15 to 32 mole % of at least one copolymerizable ethylenically unsaturated hydrocarbon and about 3 to 10 mole % of at

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least one copolymerizable monomer containing a carboxyl or amido group. The second adherent slip coating disclosed is the reaction product of about 76 to 94 mole % of a copolymerizable vinyl or vinylidene halide, about 8 to 11 mole % of acrylonitrile and about 2 to 12 mole % of at least one acrylic monomer. The second adherent coating provides an inner coating on gloves that facilitates wet donning.

Antimicrobial and antiviral gloves are well known It is especially necessary that surgeon's 10 gloves be free of bacteria or other microorganisms during surgery. Prior to donning his gloves, a surgeon scrubs his hands with a strong bactericidal soap using Then, using sterile a brush and/or a sponge. techniques, he dons his gloves which have been 15 presterilized in the package. If these steps are strictly adhered to, the surgeon's gloves do not convey bacteria to the wound or incision site. regardless of the amount of scrubbing the surgeon undertakes, bacteria remain embedded deep within the 20 pores of his hands and skin. Unfortunately, these bacteria cannot be removed via scrubbing. Once the surgeon dons his gloves, the bacteria percolate out of the pores and reinfect the surgeon's hands. bacteria do not present a hazard to the surgeon, but 25 rather a hazard to the patient if the glove were to rip, tear or puncture during surgery.

In the same light, antiviral gloves are used by physicians, nurses and other healthcare professionals who may come in contact with viruses such as AIDS or Hepatitis B during routine medical examination.

U.S. Patent No. 4,584,192 discloses a film-forming composition containing an antimicrobial agent. The antimicrobial agent disclosed is a antimicrobial agent suitable for topical application such as chlorhexidine or a suitable derivative thereof. The film comprises

of three copolymerized monomers (A, B and C). Monomer A is a monomeric acrylic or methacrylic acid ester of an alkyl alcohol containing a single hydroxyl. Monomer B is a monomeric methacrylic acid ester of an alkyl alcohol containing a single hydroxyl. Monomer C is a N-vinyl lactam.

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- U.S. Patent No. 4,675,347 discloses a antimicrobial latex composition. The antimicrobial latex composition contains at least one cationic latex component and a cationic antimicrobial agent incorporated into the latex. The cationic latex component is either a cationic natural rubber latex or a cationic synthetic natural polymer.
- U.S. Patent No. 4,853,978 discloses a
 antimicrobial multi-layered glove. The glove comprises
 an outer elastomeric coating and a inner coating. The
 inner coating has deposited on it a starch slurry
 containing antimicrobial agents thereby allowing the
 inner layer to slowly release the antimicrobial agent
 over time.
 - U.S. Patent 5,003,638 discloses a sterilized glove. Either the inside and/or outside layers of the glove contains an organic polymer film containing a antibacterial zeolite.
- U.S. Patent 5,019,096 discloses a method for producing infection resistant materials. The infection resistant materials are prepared by: (1) preparing a coating vehicle by dissolving a matrix forming polymer (such as biomedical polyurethane, biomedical silicones, biodegradable polymers) into a solvent; (2) incorporating a antimicrobial agent such as a combination of chlorhexidine and its salts and silver and its salts; (3) coating a medical device with the coating composition; and (4) drying the coated medical device.
 - U.S. Patent Nos. 5,031,245 and 5,180,605 disclose

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a natural rubber latex glove and a method for making such a glove containing a antimicrobial effective amount of a non-ionic, sparingly water soluble antimicrobial agent, such as 2,4,4'-trichloro-2'hydroxy diphenyl ether. For example, the antimicrobial agent can be incorporated into a dispersion of aqueous natural rubber latex.

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U.S. Patent No. 5,089,205 discloses a method for making a glove having antimicrobial properties. method involves dipping a former into a gelled anionic natural latex to form a outer layer and then dipping the former into a second gelled anionic natural latex. The second anionic natural latex has incorporated into it a cationic antimicrobial agent. The cationic antimicrobial agent is stabilized in the anionic gelled latex through the use of a anionic surfactant. The glove is then cured and removed from the former.

U.S. Patent Nos. 5,128,168, 5,165,953, and 5,338,565 disclose a method for forming a latex membrane having a biocide barrier. In U.S. patent No. 5,128,168, a first coating of liquid latex is applied to a former. Next, a coating of a biocide which is effective as a coagulant is applied over the first latex coating. Finally, a second coating of liquid latex is applied over the biocide and the first latex

To the coating. _U.S._Patent No. 5,165,953 is almost identical to U.S. Patent 5,128,168 however, the biocide does not function as a coagulant for the second coating. U.S. Patent 5,338,565 is almost identical to U.S. Patent number 5,165,953, except that the first and second coatings are expanded to include polymeric latex, polymers dissolved in solvent and liquid polymers.

U.S. Patent 5,133,090 discloses an antimicrobial glove having an inner coating which contains a antiviral and lubricating agent. The antiviral agent is any suitable salts of chlorhexidine such as

chlorhexidine gluconate, chlorhexidine acetate and chlorhexidine chloride. The lubricating agent facilitates donning but does not significantly absorb the antiviral agent. The inner coating is formulated in such a manner that sufficient antiviral agent is released within 10 minutes after exposure to a fluid such as blood.

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- U.S. Patent No. 5,181,276 discloses an infection resistant glove made from a molten blend of at least one polymer and a compound having antioxidant, plasticizer and antiviral activity. This compound has a hydrophilic lipophilic balance of between 12 and 20. An example of a suitable compound is nonoxynol-9.
- U.S. Patent No. 5,236,703 discloses a polymeric substrate manufactured from latex incorporating povidone-iodine. The povidone-iodine is capable of controlled release from the substrate. When contacted with a polar solution such as blood or mucous membranes, the povidone-iodine is released and functions as a biologically active agent.

SUMMARY OF THE INVENTION

This invention involves a surgical or examination glove. The glove comprises an elastomeric body in the shape of a hand which is constructed from an elastomeric polymer or copolymer such as natural rubber latex, nitrile butadiene rubber, neoprene, butyl rubber, and polyurethane.

The glove has a inner and outer surface. The inner surface is coated with a hydrophilic/hydrogel coating. The hydrophilic coating is a skin friendly coating which has moisture absorbent properties. The hydrophilic coating contains a antimicrobial or antiviral agent which protects the wearer of the glove from bacteria and viruses such as AIDS or Hepatitis.

The outer surface of the glove is coated with a fluoroelastomer. The fluoroelastomer provides an

effective barrier towards viruses and functions as an effective barrier towards body fluids due to the hydrophobic nature of its surface. An example of a fluoroelastomer that can be used in this invention is Tecnoflon TN latex available from Ausimont. Tecnoflon TN latex is a terpolymer of tetrafluoroethylene, hexa fluoropropylene and vinylidene fluoride.

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DETAILED DESCRIPTION OF THE INVENTION

The present invention involves a surgical or examination glove comprising an elastomeric body having an inner surface and an outer surface. The inner surface comprises a hydrophilic coating and the outer surface comprises a fluoroelastomer coating. The glove has plurality of superimposed layers which provide improved cleanliness, barrier properties, 'skin friendliness' and comfort. In addition, the glove has very low particulates, ion extractable, non-volatile residues and surface contaminants. Further, the glove provides improved barrier protection against microorganisms and viruses with improved comfort and skin friendliness in medical use.

The elastomeric body of the glove is made of a material that provides integrity and strength to the glove and eventually becomes the middle layer of the glove between the two coatings. The body of the glove could be made out of any elastomeric polymer or copolymer such as natural rubber latex, nitrile butadiene rubber (NBR), neoprene (CR), butyl rubber (IIR), polyurethane and the like. If natural rubber latex is used the latex can be any coagulatable natural or synthetic latex compound, coagulatable natural or synthetic rubber latexes or styrenic block copolymer dispersions known in the art. Conventional formulations for the preparation of latex are well known in the art and one skilled in the art would be readily able to vary the formulations and conditions of

curing and the like to suit the particular latex being used as well as the final article desired. Precured, partially cured, or non-cured latex can be used. Additionally, the latex may contain conventional compounding ingredients commonly utilized. Specific examples are given in U.S. Patent 3,411,982, hereby incorporated by reference.

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The inner surface of the glove, which is the skin contacting surface, comprises a hydrophilic/hydrogel polymer coating. Hydrophilic/hydrogel polymers are 10 preferred because they provide greater comfort and moisture absorption properties then other polymers. Examples of suitable hydrophilic coatings that can be used in this invention are disclosed in U.S. Patent Nos. 4,436,887, 4,499,154, 5,575,476, 4,889,664, 15 4,411,922, 4,248,685 and 4,983,332, hereby incorporated by reference. For example, polymer compositions prepared from monomers comprising hydroxy alkyl acrylates, hydroxy alkyl methacrylates, vinyl lactams (eg. vinyl pyrrolidone), acrylamide and its 20 derivatives, ethylene oxide, and the like could be These monomers impart hydrophilic properties in the copolymer. Hydrophilic polymer blends prepared from polyvinyl alcohol, polyvinylpyrrolidone and the like could also be used. The hydrophilic/hydrogel 25 polymer may or may not be cross-linked.

The hydrophilic/hydrogel polymer contains a antimicrobial or antiviral agent. According to Dorland's Medical Dictionary, 27th edition (1985), antimicrobial is defined as "(1) killing microorganisms or suppressing their multiplication or growth; and (2) an agent that kills microorganisms or suppresses their multiplication or growth." Antiviral is defined as "(1) destroying viruses or suppressing their replication; and (2) an agent that destroys viruses or suppresses their growth." Some antimicrobial agents can

be used as antiviral agents. Id. Examples of antimicrobial agents include: biguanides, including chlorhexidine and its salts, silver and its salts, polymyxin, tetracycline, aminoglycosides, rifampicin, bacitracin, neomycin, chloramphenicol, miconazole, 5 quinolones, norfloxacin, nalidixic acid, perfloxacin, enoxacin and ciprofloxacin, pencillins, nonoxynol 9, fusidic acid, cephalosporins, and combinations thereof. The antimicrobial agents would help protect against contamination from bacterial and other microbes. 10 Examples of antiviral agents include biguanide, such as chlorhexidine or a salts thereof, silver salts, such as AgSD, silver acetate, silver benzoate, silver carbonate, silver chloride, silver iodate, silver iodide, silver lactate, silver laurate, silver nitrate, 15 silver oxide, silver palmitate, and silver salts of proteins, iodine, nonoxynol-9 and combinations thereof. The antiviral agent would help protect against contamination from viruses such AIDS and Hepatitis B.

Certain additives such as emulsion silicones can also be added or coated on to the hydrophilic/hydrogel polymer used to enhance the donning and the release of the glove from the former. A silicone is generally defined as a compound that includes siloxane polymers which are based on a structure including alternate silicon and exygen atoms, with organic groups attached to the silicon. Examples of suitable silicones that can be used include polydimethylsiloxane (PDMS), Dow Corning Silicone Emulsion 365, and the like.

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The outer surface of the glove comprises a fluoroelastomer coating. Fluoroelastomers are any high polymer containing fluorine and can be homopolymers or copolymers. Fluoroelastomers exhibit elastomeric behavior or low flexural modulus. The term "fluoroelastomer" encompasses hydrogen containing fluoroelastomers as well as hydrogen-free

perfluoroelastomers. Examples of fluoroelastomers are homopolymers or copolymers of tetrafluoroethylene, hexafluoropropylene, pentafluoropropylene, chlorotrifluoroethylene, copolymers of vinylidene fluoride and hexafluoropropylene and tetrafluoroethylene and copolymers of vinylidene fluoride and chlorotrifluoroethylene.

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For example, a fluoroelastomer coating based on Tecnoflon TN latex produced by Ausimont could be used as the outer coating. This coating would provide an effective barrier towards viruses and would function as an effective barrier towards bodily fluids due to the very hydrophobic nature of its surface. Other materials which would function in a similar way include polytetrafluoroethylene(PTFE)/natural rubber latex blend, Tecnoflon TN/PTFE blend, and the like.

The elastomeric nature of the fluoroelastomer coating is beneficial because it provides deformability better than rigid plastics as well as improved frictional characteristics, such as a higher coefficient of friction, especially when compared with chlorinated natural rubber gloves.

Because of the improved barrier properties of the fluoroelastomer coating, the overall thickness of the glove could be reduced, thereby improving the tactile sensitivity and fit. Another advantage is that particles will not stick and the coating will not shred during use. Finally, another advantage of the fluoroelastomer coating is that the coating with prevent the inner layers from oxidation and ozone attack.

The fluoroelastomer coating could be cured with a variety of curing agents. These include: aliphatic diamine derivatives, aromatic dihydroxy compounds with strong alkyl and aryl bases, or their suitable derivatives, basic metal oxides and hydroxides, and

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peroxides with suitable co-agents, such as trimethylol propane, trimethacrylate, triallyl tri-mellitate.

Typical cure systems for fluoroelastomers are discussed in an article by D.S. Ogunniyi and C. Hepburn in Rubber Processing and Applications 6 (1986) pages 3-9.

For example, a typical curing agent that could be used with the Tecnoflon latex coating includes triethylene tetramine (TETA), triethylene diamine (TEDA) and the like.

While the fluoroelastomer has been described as coating the outer surface of the glove, one skilled in the art would recognize that it can also be used to coat the inner surface of the glove as well.

Although the present invention has been described primarily in connection with gloves, it can also be used to form other skin-contacting articles such as catheters, ureters, sheets, condoms, etc.

In order that the present invention may be more fully understood, the following Examples are given by way of illustration.

EXAMPLE 1

porcelain molds were washed and cleaned with soap and water to remove the smallest impurities such as minute specks of debris, oil, etc. because such debris can cause defects. The molds were rinsed with water and dried. After drying, the molds were heated and then dipped into a coagulant mixture that had been previously prepared by mixing:

	Methanol (100%)	:	76%	=
30	75.47 grams			
	Calcium Nitrate	•	16%	=
	16.06 grams			
	Calcium Carbonate	:	5%	=
	5.35 grams			
35	Lactic Acid (88%)	:	2%	=

2.87 grams

Triton X-10

1% =

0.27 grams

100%

5 100.00 grams

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After dipping, the molds were air dried under the hood approximately 5-7 minutes to evaporate the methanol in the coagulant. The molds were then again dipped into the coagulant mixture which controls the latex thickness and helps release the glove from the mold later on. The mold was air dried once again under the hood for methanol evaporation, 5-7 minutes. the molds were dipped into General Latex (Vultex 1-N-974) previously strained through a cloth sieve, gently and slowly to avoid bubbles and pinholes. When the mold emerged from the latex, an orchestrated waving motion was begun to distribute the latex evenly across the back to ensure a very thin filament coating. mold is then leached in a water bath. The mold was then placed in an oven for 15 minutes to dry and set Temperature: 250°F (121°C). Once dried, the mold was allowed to cool down. The latex glove was then dipped into a previously prepared dispersion of 50 parts of Tecnoflon TN latex and 50 parts of deionized water, wherein a 10-15 ml of amine (triethylenetetramine or diethylenetriamine) was added to 1000 ml of the dispersion. Tecnoflon TN latex is a water based emulsion of 68% fluorine terpolymer fluoroelastomer containing a minimum of 70% solids. Again, an orchestrated waving motion was used to evenly distribute. The mold was placed in the oven to cure at a temperature of 250°F (121°C) for 15 minutes. cooling, cold tap water was run through the glove while stripping it off the mold. The water layer on the glove prevents the coating from sticking to itself

during release. (Note: Triton X-100 was also used as an alternative to release the glove from the mold without sticking.) The fluoroelastomer coating was clear, smooth and exhibited a glassy coating. The fluoroelastomer coating exhibited good anchorage to the latex and did not delaminate.

EXAMPLE 2

A preformed Latex glove was slipped in, flexed and stretched into a bisque finish glove mold. Solutions of Teflon PTFE 30 and General Latex (Vultex 1-N-974) were prepared in disposable plastic beakers at different proportions such as:

- a) 600 ml General Latex + 400 ml Teflon 30
- b) 650 ml Teflon 30 + 350 ml General Latex
- c) 750 ml Teflon 30 + 250 ml General Latex
- d) 800-900 ml Teflon 30 + 200-100 ml General

Latex

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The glove mold was then dipped into the sample mixture slowly to avoid bubbles and pinholes, and orchestrated in a waving motion for even distribution when it emerges from the mixture. Next, the mold was placed in an oven to cure, typically, at 120°C (250°F) for approximately, 10 - 15 minutes. The mold, was then allowed to cool down. The gloves were then inspected. Glove (a) had a glossy, slightly sticky filament coating that was very strong and adhered well to the glove. The coating did not delaminate. Glove (b) had a glossy, slightly sticky filament coating that adhered well to the glove and was very strong. The coating did not delaminate. Glove (c) had a glossy, slightly sticky coating that stuck to itself. The coating was very strong and did not delaminate. Glove (d) had a white, cracked coating. The coating exhibited poor

anchorage and delaminated.

EXAMPLE 3

The antimicrobial glove of this invention could be prepared as follows:

If the fluoroelastomer coating is to be on the 5 outer surface after reversing, this can be accomplished by dipping the mold into a fluoroelastomer coating such as Tecnoflon TN latex. After withdrawal from the fluoroelastomer, the mold is dipped into a water or alcohol based coagulant. After the dip in the 10 coagulant, the mold is dipped into natural rubber The length of time the former is immersed in the latex determines the thickness of the glove. longer the dwell time period, the greater the wall thickness of the article, and vice versa. The mold is 15 removed from the latex with a coating of gelled latex adhering to it. The mold is placed in a water bath to leach out water soluble components such as proteins, electrolytes, etc. After the leach bath, a hydrophilic/hydrogel polymer such as hydrophilic 20 polyurethanes or acrylic such as copolymers of 2hydroxyethyl methacrylate with methacrylic acid of 2ethylhexyl acrylate or with both methacrylic acid and 2-ethylhexyl acrylate. The hydrophic/hydrogel polymer contains an antimicrobial or antiviral agent. 25 the hydrophilic coating is applied the glove is cured or dried. Once dried, the glove can be stripped from In order to enhance the release of the the former. glove from the former, powder such as cornstarch or calcium carbonate, or silicones, such as polydimethyl 30 siloxane can be added.

Although the invention has been described primarily in connection with the special and preferred embodiments, it will be understood that it is capable of modification without departing from the scope of the

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invention. The following claims are intended to cover all variations, uses, or adaptions of the invention, following, in general, the principles thereof and including such departures from the present disclosure as come within known or customary practice in the field to which the invention pertains, or as are obvious to persons skilled in the field.

CLAIMS:

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- 1. A surgical or examination glove comprising an elastomeric body in the shape of a hand having an inner surface and an outer surface, the inner surface
- comprising a coating of a hydrophilic polymer containing an antimicrobial or antiviral agent and the outer surface comprising a coating of a fluoroelastomer.
- 2. The glove of claim 1 wherein the elastomeric body
 is constructed from a polymer selected from the group
 consisting of: natural rubber latex, nitrile butadiene
 rubber, neoprene, butyl rubber, and polyurethane.
 - 3. The glove of claim 1 wherein the antiviral agent is selected from the group consisting of: chlorhexidine or salts thereof, silver salts, iodine, nonoxynol-9 and combinations thereof.
 - 4. The glove of claim 1 wherein the antimicrobial agent is selected from the group consisting of: biguanides, silver and its salts, polymyxin,
- tetracycline, aminoglycosides, rifampicin, bacitracin, neomycin, chloramphenicol, miconazole, quninolones, norfloxacin, nalidixic acid perfloxacin, enoxacin, ciprofloxacin, pencillins, nonoxynol 9, fusidic acid, cephalosporins, and combinations thereof.
- 5. The glove of claim 1 wherein the fluoroelastomer is homopolymer or copolymer selected from the group consisting of: tetrafluoroethylene, hexafluoropropylene, pentafluoropropylene, chlorotrifluoroethylene, copolymers of vinylidene
- fluoride and hexafluoropropylene, and tetrafluoroethylene and copolymers of vinylidene fluoride and chlorotrifluoroethylene.

pct/US 96/01387

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A41D19/00 B32B25/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 6 B32B A41D A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO,A,89 04647 (STILLMAN) 1 June 1989 see page 1, line 2 - page 2, line 15-20; claims 1,4,6,13,14,16; example 2 see page 3, line 18-28 - page 4, line 20 see page 6, line 7 - page 8, line 5	1-5
Y	EP,A,O 328 421 (THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK) 16 August 1989 see page 3, line 15-25; claims 1,6,7,11,13,19,21,24,27 see page 4, line 10 - page 5, column 35-37; claim 32 see page 11, line 33-62 see page 13, line 29 - page 14, line 49; examples 2,3,6 see page 22, line 10-50; examples	1-5

X Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
* Special categories of cited documents: 'A' document defining the general state of the art which is not considered to be of particular relevance 'E' earlier document but published on or after the international filing date 'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) 'O' document referring to an oral disclosure, use, exhibition or other means 'P' document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family
Date of the actual completion of the international search	Date of mailing of the international search report
12 June 1996	2 6 -06- 1996
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentiaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Authorized officer Derz, T

INTERNATIONAL SEARCH REPORT

I sational Application No PCT/US 96/01387

		PC1/05 96/0138/	
C.(Continue	DOCUMENTS CONSIDERED TO BE RELEVANT		
Category '	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	
Y	EP,A,O 141 628 (UNITIKA LTD.) 15 May 1985 see page 4, line 4 - page 5, line 25; claim 1 see page 8, line 21 - page 10, line 15 see page 15, line 5-11 - page 18, line 7-11 see page 19, line 8-9	1-5	
Υ	US,A,5 133 090 (MODAK ET AL.) 28 July 1992 cited in the application see column 2, line 30-66; claims 1,4,8,9	2-4	
Y	EP,A,O 300 814 (SURGIKOS INC.) 25 January 1989 see page 3, line 20-64; claims 1-3	2-4	
Y	WO,A,91 17047 (BRUNSWICK CORP.) 14 November 1991 see page 5, line 6-9; claims 1,4,5,12; figure 1	1,2,5	
Y	WO,A,90 14048 (BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM) 29 November 1990 see page 4, line 6-29; claims 1-4,6,11,15	2-4	
Y	WO,A,94 20574 (BAXTER INTERATIONAL INC.) 15 September 1994 see page 1, line 4-29 - page 8, line 21-30; claims 1,2,4,9,10,13	1-5	
P,Y	WO,A,95 31102 (THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK) 23 November 1995 see claims 1,2,12	1-4	

INTERNATIONAL SEARCH REPORT

Information on patent family members

etional Application No PCT/US 96/01387

Patent document cited in search report	Publication date	Patent family Publication member(s) date	
•	01-06-89	AU-B- 2727588	14-06-89
WO-A-8904647	01-00-03	MU-D- 2/2/300	14-00 05
EP-A-328421	16-08-89	US-A- 5019096	
• • • • • • • • • • • • • • • • • • • •	-	AU-B- 2989589	
	•	JP-A- 201707	
		JP-B- 7090039	
		US-A- 5133090	
		AU-B- 636767	
		AU-B- 7922991	03-10-91
EP-A-141628	15-05-85	JP-B- 601181	16-02-94
EL-W-141050	13-03-03	JP-A- 60094460	
•		JP-C- 1645557	28-02-92
		JP-B- 3010342	
	•	JP-A- 60096258	
		US-A- 4675347	23-06-87
ue 4 5133666	00 07 00	US-A- 5019090	28-05-91
US-A-5133090	28-07 - 92	AT-T- 120352	
		AU-B- 635423	
		AU-B- 773409	
		CA-A- 2043129	19-01-92
•	•	DE-D- 69108469	
		DE-T- 69108469	
		EP-A- 0467869	
		JP-A- 4241854	
		JP-B- 6057220	
		AU-B- 2989589	• • • • • • •
		EP-A,B 032842	
		•••	
		JP-B- 7090039 AU-B- 636763	
		AU-B- 792299	•••
		MA. D. APPAS	
EP-A-300814	25-01-89	US-A- 485397	
		AT-T- 11381	
- -	•	AU-B- 60434	
		AU-B- 1925186 CA-A- 130200	
		CA-A- 130200	, טב-טס-עב

INTERNATIONAL SEARCH REPORT

Information on patent family members

PCT/US 96/01387

Patent document cited in search report	Publication date	Patent family Pu member(s)		Publication date
EP-A-300814		DE-T- ES-T- JP-A- JP-B-	3852067 2063037 1043250 3044527	16-03-95 01-01-95 15-02-89 08-07-91
WO-A-9117047	14-11-91	US-A- AU-B-	5168010 7890291	01-12-92 27-11-91
WO-A-9014048	29-11-90	AU-B- US-A- US-A- US-A-	5672790 5483697 5486322 5459879	18-12-90 16-01-96 23-01-96 24-10-95
WO-A-9420574	15-09-94	CA-A- EP-A- JP-T-	2134074 0643743 7506642	15-09-94 22-03-95 20-07-95
WO-A-9531102	23-11-95	US-A- AU-B-	5487896 2637095	30-01-96 05-12-95